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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,430	11/09/2000	Shuji Hanada	11151/5	5650

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KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

[REDACTED] EXAMINER

WILKINS III, HARRY D

ART UNIT	PAPER NUMBER
1742	17

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/710,430	HANADA ET AL.
	Examiner Harry D Wilkins, III	Art Unit 1742

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 October 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3 and 8-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3 and 8-16 is/are rejected.
- 7) Claim(s) 2 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 09 September 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) Interview Summary (PTO-413) Paper No(s) _____ .
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____ .

DETAILED ACTION

1. Claims 1-3 and 8-16 are pending.
2. The rejections under 35 USC 102 and 103 based on the Araya et al reference have been withdrawn in view of the amendment filed 15 October 2002. Araya et al specifically teach away from increasing the Sn content above 5 wt%, which corresponds to about 2.5 at%.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nakanishi et al (JP 58-157934 A).

Nakanishi et al anticipate the invention as claimed. Nakanishi et al teach (see English abstract) an Ti-Ni alloy that contains up to 15 wt% Nb or Ta and up to 8 wt% Sn. Based on the disclosure of Nakanishi et al in Table 1 (page 3) the alloy contains 45 wt% Ti, with the balance being Ni. Such an alloy (with 15 wt% Nb, 8 wt% Sn, 45 wt% Ti, balance Ni) contains 3.93 at% Sn and 9.42 at% Nb. Regarding the shape memory properties of the alloy, Nakanishi et al teach (see title) a shape memory alloy. It is well known in the art that Nitinol (Ti-Ni shape memory alloys) have shape memory and superelasticity properties at human body temperature (for support, see Dotter, at col 5, lines 10-21). Regarding the presence of Ni in the alloy of Nakanishi et al, the present

claim recites "comprising" which is read to leave the composition open to other elements, even in major amounts.

Regarding claim 3, the alloy of Nakanishi et al contains 9.42 at% Nb.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi et al (JP 58-157934 A) in view of Farzon-Nia et al (US 5,429,504).

As cited above, Nakanishi et al do not teach that an orthodontic appliance is made of the claimed alloy.

Farzin-Nia et al teach (see col 2, lines 19-33) orthodontic applications for a titanium-based material which may contain tin and niobium.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Nakanishi et al for the well known purpose of orthodontic appliances as taught by Farzin-Nia et al because the alloy of Nakanishi et al has shape memory characteristics and is bio-compatible (for support see Dotter, at col 5, lines 10-21).

7. Claims 9, 10, 11 and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi et al (JP 58-157934) in view of Araya et al (JP 10-219375).

As cited above, Nakanishi et al do not teach that an artificial dental implant, an artificial arthrosis, a bone material or artificial joints are made of the claimed alloy.

Regarding claim 9, Araya et al teach (see English abstract) that the alloy composition is useful as a dental root.

Regarding claims 10 and 16, Araya et al teach (see English abstract) that the alloy composition is useful as an artificial joint. An arthrosis, as defined by Merriam Webster's Collegiate Dictionary, 10th Edition, is an articulation between bones. The same defines articulation as a joint or juncture between bones or cartilages in the skeleton. Thus, an artificial arthrosis is another way of saying artificial joint.

Regarding claim 11, Araya et al teach (see English abstract) that the alloy is useful as a substitutive material for bone.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Nakanishi et al for the well known purposes of artificial dental implants, artificial arthroses, bone material or artificial joints as taught by Araya et al because the alloy of Nakanishi et al has shape memory characteristics and is bio-compatible.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi et al (JP 58-157934) in view of Beyar et al (US 6,127,597).

As cited above, Nakanishi et al do not teach that a bone fixator is made of the claimed alloy.

Beyar et al teach (see col 3, lines 16-25) that bone fixators have been known to be made of titanium or nitinol (a shape memory alloy).

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Nakanishi et al for the well known purpose of a bone fixator as taught

by Beyar et al because the alloy of Nakanishi et al has shape memory characteristics and is bio-compatible.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi et al (JP 58-157934) in view of Regan (US 4,795,458).

As cited above, Nakanishi et al do not teach that a thrombus inhibitor (i.e.-stent) is made of the claimed alloy.

Regan teaches (see col 1, lines 51-53) that stents are well known to be made of nitinol, a shape memory alloy of nickel and titanium.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Nakanishi et al for the well known purpose of stents as taught by Regan because the alloy of Nakanishi et al has shape memory characteristics and is bio-compatible.

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi et al (JP 58-157934) in view of Kizelshteyn et al (US 5,215,105).

As cited above, Nakanishi et al do not teach that a catheter introducer is made of the claimed alloy.

Kizelshteyn et al teach (see col 3, lines 58-64) that it is well known in the art to make catheter introducers from shape memory alloys.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Nakanishi et al for the well known purposes of a catheter introducer as taught by Kizelshteyn et al because the alloy of Nakanishi et al has shape memory characteristics and is bio-compatible.

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi et al (JP 58-157934) in view of Besselink et al (US 5,551,871).

As cited above, Nakanishi et al do not teach that a Harrington bar (i.e.-a device to correct scoliosis) is made of the claimed alloy.

Besselink et al teach (see col 3, line 58 to col 4, line 22) that shape memory alloys, such as titanium-nickel-niobium, are useful as a scoliosis correction system inside a patient's body where repeated adjustment is often not necessary or desirable but stability is. A standard type of scoliosis correction is the use of a Harrington bar, as evidenced by Applicant's admission (see specification page 7, lines 4-6).

Therefore, it would have been obvious to one of ordinary skill in the art to have used the alloy of Nakanishi et al for the well known purpose of a Harrington bar as taught by Besselink et al because the alloy of Nakanishi et al has shape memory characteristics and is bio-compatible.

Allowable Subject Matter

12. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: the closest prior art consists of Araya et al (JP 10-219375) and Nakanishi et al (JP 58-157934). Araya et al do not teach the limitation that Sn is included at 3-6 at%, and in fact directly teach away from including more than 2.5 at%. Nakanishi et al teach directly away from including a large amount of Ti in the alloy. Particularly in Table 1

(page 3) it can be seen that the alloy contains 45 wt% Ti, which equates to about 55 at%, well below the claimed range of 74-90 at%. Therefore, claim 2 would be allowable over the prior art if rewritten in independent form.

Response to Arguments

14. Applicant's arguments with respect to claims 1-3 and 8-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Harry D Wilkins, III whose telephone number is 703-305-9927. The examiner can normally be reached on M-Th 6:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy V King can be reached on 703-308-1146. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Harry D Wilkins, III
Examiner
Art Unit 1742

hdw
November 20, 2002

R
ROY KING
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700